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EXAMINER

HAMUD, FOZIA M

ART UNIT PAPER NUMBER

1647

DATE MAILED: 02/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/087,782

Applicant(s)

ROSIER ET AL.

Examiner

Fozia M Hamud

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/04/03.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24, 41 is/are pending in the application.
- 4a) Of the above claim(s) 2-6, 8-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 7, 17-24, 41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Receipt of Applicant's amendment and arguments, filed on 07 November 2003, is acknowledged. Claims 2-3, 15, 16 and 21 have been amended, claims 25-40 have been cancelled and new claim 41 has been added. Thus claims 1-24 and 41 are pending of which claims 1, 7, 17-24 and 41 are under consideration.

Claims 8-16 stand withdrawn from consideration, and claims 2-6 are withdrawn from consideration, by the Examiner as they are drawn to non-elected inventions.

Election/Restriction:

2a. Applicants elected with traverse to prosecute the nucleic acid comprising SEQ ID NO:1, in Paper No.9, filed on 20 June 2003. The traversal was not found persuasive in the office action mailed on 11 August 2003. In this response (filed on 07 November 2003), Applicants again traverse the restriction between SEQ ID Nos: 1-30, and argue that these sequences are all related. Applicants further submit that in the event that the Examiner does not reconsider the restriction between SEQ ID Nos;1 through 30, then, at least 10 of the sequences should be examined in accordance with MPEP § 803.04.

2b. Applicants' traversal has been considered fully, but is not found persuasive.

Firstly, according to MPEP § 803.04 (Restriction - Nucleotide Sequences), by statute, "[if two or more independent and distinct inventions are claimed in one Application, the Commissioner may require the application to be restricted to one of the inventions]". Thus pursuant to 35 U.S.C. 121, the rules provide that if two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant to elect that invention to which his claim shall be

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restricted, see 37 CFR 1.142(a). See also 37 CFR 1.141(a). Therefore, since SEQ ID Nos:1-30, recited in instant claims are distinct products that are not obvious over one another, claims reciting these sequences are subject to restriction requirement under 35 U.S.C. 121. Furthermore, the multitude of the presently claimed sequences present a serious search burden.

Secondly, the issue addressed in MPEP § 803.04 was a partial waiver of restriction practice to allow examination of up to ten sequences. This waiver was issued in 1996. Since then, the nucleic acid and protein databases that must be searched for each of the independent and distinct sequence claimed herein have multiplied many fold in size, such that it is now burdensome to search more than a single sequence in an application. Further, the waiver allowed, but did not require the Examiner to search ten sequences.

2c. Applicant's reservation of the right to prosecute the claims of Groups III, IV, V, VI and VII in divisional applications is acknowledged.

2d. The elected invention is an isolated nucleic acid molecule, comprising the nucleotide sequence set forth in SEQ ID NO:1. Therefore, claims 1, 7, 17-24 and 41 are drawn to the elected invention. Claims 2-6 are currently withdrawn from prosecution, because these claims are drawn to non-elected SEQ ID Nos:2-29. Claims 8-16 were previously withdrawn from prosecution as being drawn to non-elected inventions. As was set forth in the previous office action, in the event where the product of Group I is found allowable, method claims of making and using the nucleic acid of Group I will be rejoined, so long as the method claims do not precipitate new grounds of rejections.

Status of Claims:

2e. Claims 1-24, 41 are pending. Claims 1, 7, 17-24 and 41 are under consideration. Claims 2-6 and 8-16 are withdrawn from prosecution as being drawn to non-elected inventions.

Response to Applicants' arguments:

Claim objections

3a. Claims 1, 7, 17-20 stand objected to because of the following informalities:

Claims 1 and 7 are objected to because they recite non-elected SEQ ID Nos.

Claims 17-20 are objected to, insofar as they depend on claim 1.

4. The following previous objection is withdrawn in light of Applicants amendments filed on 11/07/03:

(I) All of the rejections made against claims 2-6 are withdrawn, because these claims are withdrawn from further consideration since they are drawn to non-elected SEQ ID Nos.

Claim Rejections - 35 U.S.C. § 101/112:

35 U.S.C. 101 reads as follows:

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5a. Claims 1, 7, 17-24 stand rejected and new claim 41 is also rejected under 35 U.S.C. 101, for reasons of record, set forth in the office action mailed on 08/11/03, pages 4-6, and reiterated here, because the claimed invention is not supported by either

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a specific and substantial asserted utility or a well established utility. Applicants submit the following arguments regarding this rejection.

Applicants argue that the claimed nucleic acids are useful not only for expressing the ABCC11 protein, but also for identifying the 16q12 locus on human chromosome 16, and investigating changes at this locus, which provides a specific, credible and substantial utility for the claimed nucleic acids. Applicants contend that it would be apparent to one of skill in the art upon reading the present specification that the presently claimed nucleic acids could be used to determine or confirm the location of other genes on human chromosome 16, particularly those in the 16q12 region. With respect to vectors and cells of the present invention, Applicants submit that they are useful for producing nucleic acids that are specific for the ABCC11 gene, and thus are useful for producing the ABCC11 specific probes. Thus Applicants argue that the claimed nucleic acids, vectors and host cells have well known utility or a specific, credible and substantial utility.

Applicants' arguments have been fully considered but are deemed unpersuasive. Firstly, using the claimed nucleic acid as a chromosomal marker does not provide the claimed invention a specific utility, because no meaningful information will be obtained from tracking the level of expression of the claimed nucleotide, or identifying other genes that map on this locus, because there is no physiological or biological significance attached to the claimed nucleic acid or the encoded protein. Applicants have not shown whether the claimed nucleic acid is associated with only normal conditions or whether it is associated with abnormal conditions, mapping to

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chromosome 16q12. Applicants have not disclosed conditions in which the claimed nucleic acid is either deleted or rearranged. Instant specification only discloses that claimed nucleic acid maps on human chromosome 16, 16q12. However, Applicants have not disclosed whether said nucleic acid is involved in any disorder that maps to this chromosome. Furthermore, since the claimed nucleic acid lacks specific and substantial utility, vectors and host cells that are transformed with the claimed nucleic acid and probes that are specific for the claimed nucleic acid also lack specific and substantial utility.

Therefore, the claimed nucleic acid lacks substantial utility, because Applicants have not taught which, if any, abnormalities that map to chromosome 16q12 can be identified using the claimed nucleic acid.

5b. Claims 1, 7, 17-24 also stand rejected under 35 U.S.C. 112, first paragraph, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Specifically, the fact that claimed nucleic acid maps on human chromosome 16, 16q12, does not provide specific or substantial utility for the claimed nucleic acid, because there is no information establishing a link between the claimed nucleic acid and any disease state. Thus, one of ordinary skill in the art would not know how to use the claimed nucleic acid, or vectors and host cells comprising said nucleic acid or probes that are specific for the claimed nucleic acid.

Claim Rejections - 35 U.S.C. §112:

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6a. Claim 7 stands rejected under under 35 U.S.C. 112, second paragraph, for reciting "ABCC11 ...", which renders the claim unclear, because more than one gene can be known for the same acronym. Applicant is advised to recite the full name of the gene corresponding to this acronym in the claim, to obviate this rejection.

Conclusion:

7. No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday, Wednesday-Thursday, 6:30 am to 4:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4227.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Fozia Hamud
Patent Examiner
Art Unit 1647
14 January 2004


GARY KUNZ
SUPERVISORY PATENT EXAMINER
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